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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,099

03/19/2007

Osamu Kanome

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07/29/2009

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EXAMINER

LAM, ANN Y

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,099	<b>Applicant(s)</b> KANOME ET AL.	
	<b>Examiner</b> ANN Y. LAM	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13, drawn to a cell culture substrate.

Group II, claim(s) 14-17, drawn to a method for producing a cell culture substrate.

Group III, claim(s) 18-25, drawn to a method for screening a cell culture condition.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The technical feature linking groups I-III appears to be that they all relate to a cell culture substrate having at least one area for culturing a cell on a substrate characterized in that the culturing area comprises an area for holding a biologically active substance having a biological activity to the cell and an area for immobilizing a biologically active substance having a biological activity to the cell.

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However, this apparatus is disclosed by Thigpen et al., U.S. patent 6,171,856.

Thigpen et al. teach screening methods may use cells as adherent cells on a culture dish, in 96-well assay plates, as part of an alginate biomatrix in suspension culture or in any other form that permits the cell proliferation or cell death to be monitored. These cells are used as reagents to screen small molecule and peptide libraries to identify inhibitors and other modulators of free fatty acid (FFA) induced inhibition of glucose-induced .beta.-cell proliferation and/or FFA induced .beta.-cell death (col. 86, lines 22-29.) Thigpen et al. specifically disclose a method for determining the ability of a candidate substance to inhibit FFA induced .beta.-cell destruction, dysfunction, or proliferation inhibition, wherein the method includes generally the steps of: (i) providing a glucose responsive .beta.-cell (ii) contacting said cell with a) a candidate substance; and b) free fatty acid (FFA) in an amount sufficient to induce inhibition of glucose induced .beta.-cell proliferation; (iii) comparing the proliferation of said cell in step (ii) in the presence and absence of said candidate substance (col. 86, lines 49-61.) It is understood that the alginate biomatrix is held on a support/substrate. The alginate biomatrix comprises an area for culturing a cell since it is capable of holding a cell and permitting introduction of any necessary reagents. Moreover, a subarea of the alginate biomatrix is considered to be an area for holding [i.e., capable of holding] a biologically active substance having a biological activity to the cell and another subarea of the alginate biomatrix is considered to be an area for immobilizing a biologically active substance having a biological activity to the cell.

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Therefore, the technical feature linking the inventions of groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a cell culture substrate having at least one area for culturing a cell on a substrate characterized in that the culturing area comprises an area for holding a biologically active substance having a biological activity to the cell and an area for immobilizing a biologically active substance having a biological activity to the cell.

The special technical feature of group II is considered to be a method for producing a cell culture substrate, the method including using a liquid discharge means for providing a biologically active substance to at least one of the holding area and the immobilizing area.

The special technical feature of group III is considered to be a method for screening a cell culture condition, the method comprising filling the culture area with a culture liquid and culturing the cells in a state where a biologically active substance immobilized in an immobilizing area of the culture area is in contact with the culture liquid, and contacting the culture liquid with the holding area thereby liberating a biologically active substance in the holding area into the culture liquid.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Thurs., 9-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/  
Primary Examiner, Art Unit 1641